

I claim:

1. A method for obtaining a biologically active botulinum toxin,
5 comprising the steps of:
 - (a) providing a fermentation medium that is substantially free
of an animal derived product;
 - (b) culturing a Clostridium botulinum bacterium in the
fermentation medium under conditions which permit
10 production of a botulinum toxin, and;
 - (c) recovering a biologically active botulinum toxin from the
fermentation medium.
2. The method of claim 1, wherein in the step of providing a fermentation
medium, the medium comprises a protein product derived from a
15 vegetable.
3. The method of claim 2, wherein the vegetable is a soybean.
4. The method of claim 1, wherein in the step of culturing, the culturing is
20 performed until cell density of the culture decreases due to cell lysis.
5. The method of claim 1, wherein in the step of culturing, the culturing is
performed until at least 48 hours after initial drop in cell density due to
cell lysis.
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6. A method for production of a botulinum toxin, the method comprising
steps of:
 - (a) providing a first medium that is substantially free of an
animal derived product and that comprises a protein
30 product derived from a vegetable;
 - (b) culturing a Clostridium botulinum bacterium the first
medium under conditions that permit growth of the

Clostridium botulinum;

- (c) providing a second medium that is substantially free of an animal derived product and that comprises a protein product derived from a vegetable;
- 5 (d) inoculating the second medium with the first medium;
- (e) culturing a Clostridium botulinum bacterium in the second medium under conditions that allow production of a botulinum toxin, and;
- (f) recovering the botulinum toxin.

10 7. The method of claim 6, wherein in the step of providing a first medium, the first medium comprises a protein product derived from a soybean, and wherein in the step of inoculating the second medium, the second medium comprises the protein product derived from a soybean.

15 8. The method of claim 6, wherein in the step of providing a first medium, the first medium comprises a hydrolyzed soy, and wherein in the step of inoculating a second medium, the fermentation medium comprises hydrolyzed soy.

20 9. The method of claim 6, wherein in the step of culturing a Clostridium botulinum in a first medium, the conditions comprise a temperature of about 34 degrees Celsius, and further comprise no decrease in cell density during culturing,

25 wherein in the step of inoculating a second medium with a first medium, 2 to 4 percent of the first medium is used to inoculate the second medium, and wherein in the step of culturing the bacterium in the second medium, the

30 conditions that allow growth comprise a temperature of approximately 34 degrees Celsius and further comprise culturing until cell density of the culture decreases due to cell lysis.

10. A composition comprising a *Clostridium botulinum* and a culture medium for producing a botulinum toxin wherein the medium is substantially free of an animal derived product and comprises a protein product derived from a vegetable.

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11. The composition of claim 10, wherein the vegetable is a soybean.

12. The composition of claim 10, wherein the composition comprises a hydrolyzed soy.

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13. A method for making a substantially animal product free pharmaceutical composition in which the active ingredient is a botulinum toxin, the method comprising the steps of:

15 (a) obtaining a biologically active botulinum toxin by:

(i) providing a fermentation medium that is substantially free of an animal derived product;

(ii) culturing a *Clostridium botulinum* in the fermentation medium under conditions which permit production of a botulinum toxin, and;

20 (iii) recovering a biologically active botulinum toxin from the fermentation medium;

(b) formulating the botulinum toxin with a suitable excipient, thereby making a substantially animal product free pharmaceutical composition in which the active ingredient is a botulinum toxin.

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